UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE THE OPINIONS OF DAVID MADIGAN, PH.D.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Rules

Defendants' Executive Committee, on behalf of all Defendants in this litigation, respectfully submits this Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of David Madigan, Ph.D., pursuant to Federal Rules of Evidence 104, 403, and 702 ("Motion").[1]

INTRODUCTION

The only issue before the Court at this stage is general causation. Plaintiffs' statistical expert, Dr. David Madigan, Ph.D, has disclosed no qualified, relevant, or reliable opinions to assist the Court on that issue. Plaintiffs directed Dr. Madigan to perform a statistical analysis of certain designated dietary and occupational studies hand-picked for his review by another of Plaintiffs' experts. From his review, Dr. Madigan offers opinions about the purported strength of association and dose-response between exposure to NDMA and/or NDEA and certain cancers at issue in this litigation (Madigan Rep. ¶ 7).[2] Dr. Madigan's litigation-driven analysis concludes "it is scientifically plausible" that users of valsartan with NDMA impurities "could develop cancer."[3] (Madigan Rep. ¶ 35). Dr. Madigan's opinions and conclusion fail to satisfy Plaintiffs' burden of demonstrating qualification,

[1] A copy of Plaintiffs' Designation of Experts and Opinion Testimony, served July 12, 2021, is attached as Ex. A.

[2] A copy of Dr. Madigan's Expert Report (the "Madigan Rep.") is attached as Ex. B.

[3] Notably, Dr. Madigan's conclusion references "cancer" generally without individualized analysis as to the supposed risk of any particular type of cancer at issue in this case.

reliability, and fit, and should be excluded in their entirety.

By his own admission Dr. Madigan is not qualified to offer a general causation opinion, and, according to him, he has none. He is not a medical doctor, epidemiologist, or toxicologist, and he does not have the necessary training and experience to offer testimony regarding whether exposures to NDMA and/or NDEA cause cancer. His purported "strength of association" statistical analysis does not and cannot demonstrate general causation, and is therefore either wholly irrelevant or, insofar as it is a disguised epidemiological opinion, entirely outside of Dr. Madigan's field. Additionally, no other expert offered by Plaintiffs relies on Dr. Madigan's statistical analysis in offering his own conclusions. As such, Dr. Madigan's opinions are not foundational to other experts or otherwise relevant to their own conclusions. Thus, Dr. Madigan is unqualified to assist the Court at this stage of the proceedings, and the opinions he has disclosed do not fit the general causation issue this Court is presently deciding.

Dr. Madigan's methodology is also unreliable. He concedes his methodology was driven not by scientific principles or methods, but by the assignment given to him by Plaintiffs' counsel. He performed a litigation analysis of studies chosen for him and uncritically accepted by him—not a scientific examination of all relevant epidemiological literature to ascertain "strength of association" across all germane studies. Indeed, he admits he knew of and patently ignored the key epidemiological

literature that squarely addresses whether there is an increased risk associated with valsartan containing NDMA and/or NDEA. He further relies upon and parrots the conclusions of other Plaintiffs' experts without vetting the reliability of their opinions or conducting any research. And he leaps to an inferential conclusion about the application of his analysis to valsartan that is unsupported by any scientific analysis or methods, or anything beyond Dr. Madigan's unsubstantiated say-so.

Finally, Dr. Madigan should be excluded from testifying about subjects admittedly outside his expertise, multiple cancers at issue in this litigation that he does not address in his disclosures, and NDEA, which he largely failed to analyze. To the extent any of Dr. Madigan's opinions are ultimately admitted, the substantial majority should be excluded or narrowly limited.

SPECIFIC OPINIONS TO BE EXCLUDED[4]

Defendants move to exclude Dr. Madigan's opinions and testimony in their entirety including:

- All general causation opinions. Dr. Madigan has expressly disclaimed having any general causation opinions and is not qualified to offer such opinions;
- All "strength of association" opinions, including the opinion that, based on

[4] Defendants reserve the right to move to exclude or limit this expert witness's opinions on grounds other than those set forth herein if those grounds become available subsequent to the filing of this Motion by virtue of the Court's rulings, any additional discovery that may take place in this case, or supplementation of this expert witness's disclosure or report.

"the levels of NDMA reported in contaminated valsartan and the timeframe over which the contamination occurred, it is scientifically plausible that users of contaminated valsartan could develop cancer." (Madigan Rep. ¶ 35). That opinion is irrelevant to general causation, an epidemiology opinion outside of Dr. Madigan's expertise, and wholly unsupported by any scientific analysis;

- All opinions based on a "statistical analysis" of only specific epidemiological literature selected for him by another of Plaintiffs' experts and accepted by him uncritically while knowingly excluding other relevant literature. Such opinions are litigation opinions, not expert scientific opinions grounded in scientific methodology, and thus are inherently unreliable;
- The opinion that inhaled nitrosamine exposure reflected in occupational studies is medically or toxicologically similar to orally ingested NDMA and/or NDEA in pharmaceuticals. Dr. Madigan has neither the qualifications nor a scientific or methodological basis for such opinions and is merely parroting the conclusions of Plaintiffs' other experts;
- Any opinions regarding a purported association between NDMA and/or NDEA and cancer of the bladder, breast, blood, kidney, pharynges, prostate, or uterus. According to his own report, Dr. Madigan has not analyzed any medical literature assessing the alleged association between NDMA and/or NDEA and these cancers, and thus has no basis to offer such opinions;

- Any opinions regarding a purported association between NDEA and *any* cancer. Dr. Madigan has not reviewed any literature or done any analysis concerning any such purported association, except as to pancreatic cancer, and that study was significantly limited, as he conceded at deposition; and
- Any regulatory opinions. Dr. Madigan has conceded that he is not offering any opinions about regulatory compliance or Food and Drug Administration ("FDA") rules and regulations.

Additionally, Dr. Madigan has conceded that he is not an expert concerning (and, as such has no basis to offer any opinions on):

- Medicine, including pathology, oncology, hematology, cell biology, toxicology, pharmacology, or pharmacokinetics;
- Current good manufacturing practices; and/or
- The "root cause" analysis of the source of any NDMA and/or NDEA impurity in any manufacturer's valsartan.

(Madigan Dep. at 230:15-231:20, 233:8-16, full deposition transcript attached as Ex. C).

FACTUAL AND PROCEDURAL BACKGROUND

Defendants hereby adopt and expressly incorporate by reference the "Factual and Procedural Background" set forth in the Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of Stephen Hecht, Ph.D.

LEGAL STANDARDS

In addition to the legal standards set forth herein, Defendants incorporate by reference the section entitled "Legal Standards" set forth in the Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of Stephen Hecht, Ph.D.

Under Federal Rule of Evidence 702, this Court performs a "gatekeeping function" to ensure that all expert testimony is both relevant and reliable. *See In re Paulsboro Derailment Cases*, 746 Fed. App'x 94, 98 (3d Cir. 2018) (Vanaskie, J.) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). It is Plaintiffs' burden alone to show Dr. Madigan's testimony is admissible. *See Warren Distributing Co. v. Inbev USA L.L.C*, 2010 WL 2179167, at *3 (D.N.J. May 26, 2010) (Kugler, J.) (citing *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

"Rule 702 embodies a trilogy of restrictions on expert testimony: ***qualification***, ***reliability***, and ***fit***." *Ruggiero v. Yamaha Motor Corp., U.S.A.*, 778 F. App'x 88, 93 (3d Cir. 2019) (emphasis added) (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)). First, the Court must consider whether the expert is qualified "to render an opinion" based on his or her "specialized expertise." *In re Hum. Tissue Prods. Liability Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008) (quoting *Pineda*, 520 F.3d at 244). Though qualification is

interpreted liberally, the Third Circuit recognizes an expert who "may be generally qualified" may nevertheless "lack qualifications to testify outside his area of expertise." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 322 (3d Cir. 2003). Second, the Court must evaluate the reliability of the expert's methodology. For an expert to be reliable, his opinions must be based on methods and procedures of science rather than on subjective belief or unsupported speculation. The expert must have "good grounds" for his or her belief. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 732 (3d Cir. 1994) (quoting *Daubert*, 509 U.S. 579 at 590). Third, the Court must consider whether the expert's testimony will be helpful to the trier of fact. *See* Fed. R. Evid. 702(a). "The issue of fit 'is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.' . . . The standard for fitness is 'not that high' but is 'higher than bare relevance.'" *In re Hum. Tissue Prod. Liab. Litig.*, 582 F. Supp. 2d at 657 (quoting *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999); *In re Paoli*, 35 F.3d at 745). An opinion fits and helps the trier of fact when there is a connection between the scientific research or test result to be presented and the particular disputed factual issues in the case. *Warren Distributing Co.*, 2010 WL 2179167, at *4.

ARGUMENT

I. DR. MADIGAN IS NOT QUALIFIED TO OFFER GENERAL CAUSATION OPINIONS AND HIS OPINIONS DO NOT FIT THE GENERAL CAUSATION QUESTION BEFORE THIS COURT.

All of Dr. Madigan's opinions should be excluded in their entirety because he lacks the qualifications to give general causation opinions, which are the only opinions that "fit" at this stage of the litigation. Dr. Madigan admits he is not qualified to offer general causation opinions and expressly disclaims any such opinions. Because general causation is the only issue before the Court at this point, Dr. Madigan's testimony disqualifies him from assisting the Court at the present stage of the proceedings. Moreover, to the extent Dr. Madigan's "strength of association" opinions are intended to fulfill some quasi-causation function, they are irrelevant and unqualified epidemiological testimony.

A. Dr. Madigan Is Not Qualified To Give And Indeed Disclaims Any General Causation Opinions.

By his own admission and according to the findings of multiple courts assessing his qualifications, Dr. Madigan is not qualified to opine on general causation. *See e.g.* Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of Stephen Hecht, Ph.D. ("Motion to Exclude Hecht"), at section I(A)(1) (explaining qualifications requirement for expert testimony). Dr. Madigan is not an expert in any relevant field that can speak to medical causation, including epidemiology, pathology, oncology, hematology, cell biology, toxicology,

pharmacology, or pharmacokinetics. (Madigan Dep. at 230:15-17, 231:2-20). His qualifications are limited to statistics.

Courts have repeatedly excluded Dr. Madigan's prior efforts to offer causation opinions under the guise of similar statistical opinions to those offered in this case. For example, when Dr. Madigan disclosed similar opinions in the Abilify MDL, the court found, "Dr. Madigan lack[ed] the medical knowledge and experience to offer a general causation opinion," as he "is a man of statistics, not medicine." *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d 1291, 1361 (N.D. Fla. 2018) (excluding Dr. Madigan's general causation opinion). The court stated:

> [Dr. Madigan] is not a medical doctor, toxicologist, pharmacologist, or psychologist. He also has no specialized knowledge of, or clinical experience with, pathological gambling or impulse control disorders. The Court finds that Dr. Madigan's admitted lack of expertise in the aforementioned fields precludes him from offering a medical or scientific opinion that Abilify is capable of causing pathological gambling and impulse control disorder.

Id.

The court in *In re Vioxx Prod. Liab. Litig.*, 2016 WL 8711273, at *4 (E.D. La. Sept. 16, 2016), excluded Dr. Madigan's causation opinions on similar grounds, finding:

> Dr. Madigan is not a medical doctor. He has no clinical experience, has not held a position in a medical school, and has no experience in weighing the risks and benefits of medical treatment, including pharmaceuticals. He is not an epidemiologist and does not claim to have experience designing or conducting clinical drug trials. He is not an expert in pharmacology, cardiology, rheumatology, gastroentology,

> neurology, vascular biology, or any other medicine related to Vioxx. * * * Based on these qualifications, it is not clear what assistance Dr. Madigan can offer the fact finder in this case. Dr. Madigan's expert experience is exclusively in the fields of mathematics and statistics.

Id. at *4 (limiting Dr. Madigan's opinions to those "regarding the field of statistics, how they are compiled, and their general use").

The same is true here. Dr. Madigan does not have sufficient expertise or qualifications to testify whether it is "scientifically plausible" that exposure to NDMA or NDEA at the levels and durations relevant to this case is capable of causing the cancers alleged. He admits as much, expressly disclaiming any general causation opinions in this case. (Madigan Dep. at 280:21-24 ("Q: Dr. Madigan, what I understood your testimony to be is that you are not going to offer any general causation opinions, correct? A: Correct."). When asked whether he is qualified to give an opinion "as to whether or not nitrosamine impurities in the valsartan at issue caused or has the potential to cause cancer in humans," he answered, "Probably not. I don't understand enough about the mechanisms and so on." (*Id*. at 19:3-12). Asked to confirm he is offering no such opinions, he answered, "Correct, I'm not offering causation opinion[s]." (*Id*. at 19:14-21; *see also id*. at 19:23-20:1, *id*. at 209:6-15 ("I'm not offering an opinion the contaminated valsartan caused the cancer")). Dr. Madigan's report does not even contain the word "causation."

Because the only relevant question at this stage is general causation—whether NDMA and/or NDEA at the doses and durations of exposure experienced by

Plaintiffs is capable of causing the cancers they claim—the Court's inquiry regarding Dr. Madigan need go no further. By his own admission, Dr. Madigan is not qualified to assist the Court or a jury on this question, and expressly disclaims any causation opinions. He also has conceded he has no independent opinion about whether NDMA is or is reasonably expected to be a human carcinogen. (Madigan Dep. at 117:23-118:7). Dr. Madigan lacks the requisite qualifications and his opinions lack the requisite fit to this stage of the proceedings. His opinions should therefore be excluded in their entirety.

B. Dr. Madigan's "Strength Of Association" Opinions Are Irrelevant And Unqualified.

Having disqualified himself on the issue of causation, Dr. Madigan attempts to introduce a distinct set of "strength of association" opinions in which he purports to perform a statistical analysis of "strength of association, dose-response and increased risk of cancers reported" in the "dietary and occupational studies" selected for him to review. (Madigan Rep. ¶ 7). Dr. Madigan's analysis recites the risk estimates, hazard ratios, odds ratios, and confidence intervals from the selected studies, finds "statistically significant associations and trends" between "lifetime cumulative exposure" to NDMA and certain cancers, and concludes, "Based on valsartan dosing, the levels of NDMA reported in contaminated valsartan and the timeframe over which the contamination occurred, it is scientifically plausible that users of contaminated valsartan could develop cancer." (*Id*. ¶¶ 8-35). Putting aside

the methodological flaws in this analysis, discussed *infra*, Dr. Madigan's opinions are irrelevant and unqualified.

Dr. Madigan's putative finding of a "statistically significant association" between "lifetime cumulative exposure" to dietary and occupational NDMA and certain forms of cancer is wholly irrelevant to general causation. The "strength of association" analysis is not even an opinion that NDMA causes cancer, much less that the NDMA levels purportedly found in some forms of valsartan cause cancer. A mere association or correlation between an alleged exposure and a type of cancer is not evidence of causation. *See e.g.* Motion to Exclude Hecht, at section II(A)(3) (explaining necessity of statistical significance to support an inference of causation); *see also Peters v. Astrazeneca LP*, 224 F. App'x 503, 507 (7th Cir. 2007) (finding evidence "suggestive of a correlation" between prescription drug and alleged harm insufficient because "a correlation alone is not evidence of causation"); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 885 (10th Cir. 2005) ("A correlation does not equal causation."); *Burleson v. Tex. Dep't Criminal Justice*, 393 F.3d 577, 585-86 (5th Cir. 2004) (upholding exclusion of expert causation testimony where expert relied solely on studies showing certain cancers were "associated with" exposure to substance at issue but lacked epidemiological studies establishing causation). By Dr. Madigan's own admission, his opinion is not a causation opinion because "I don't understand enough about the mechanisms and so on." (Madigan Dep. at 19:3-12).

Thus, even were the Court inclined to overlook Dr. Madigan's flawed methodology, the "strength of association" opinion he offers is not a causation opinion and is thus irrelevant to this general causation inquiry.

Moreover, to the extent Dr. Madigan's putative statistical analysis is offered as some form of quasi-causation inquiry in place of a formal general causation opinion he is unqualified to offer, it is nothing more than a thinly-veiled epidemiological opinion he is equally unqualified to give. "Epidemiology is 'the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations'" and "is central to the general causation inquiry[.]" *In re Roundup Prod. Liab. Litig.*, 390 F. Supp. 3d 1102, 1116 (N.D. Cal. 2018) (citations omitted). Its purpose is "to discern accurately the effect of a particular agent on a disease against the background of the natural occurrence of the disease in the relevant population," meaning "epidemiology is the scientific methodology that allows testing of the hypothesis that Substance A causes Effect B." *Soldo v. Sandoz Pharmaceuticals Corp.*, 244 F. Supp. 2d 434, 533 (W.D. Pa. 2003). Dr. Madigan is not qualified to offer this Court an opinion grounded in epidemiology.

Dr. Madigan's conclusions are epidemiology opinions costumed as statistics opinions. He does not undertake an assessment of the validity of the statistical methods applied to the studies he reviewed. Rather, he spends 25 paragraphs merely

tallying the outcomes of the studies provided to him to review. (Madigan Rep. ¶¶ 8-32). He then offers three paragraphs of opinions that are patently outside the field of statistics and within the field of epidemiology, regarding what lifetime cumulative exposure thresholds to NDMA or NDEA are purportedly associated with what cancer risks, and whether it is "scientifically plausible that users of contaminated valsartan could develop cancer." (*Id*. ¶¶ 33-35).

Dr. Madigan is not an expert in epidemiology. He is not an epidemiologist by training or profession, nor is he a professor of epidemiology or a member of any professional organization in the epidemiology realm, and he does not have any degrees or certifications in epidemiology. (Madigan Dep. at 229:5-19). Prior to his retention by the plaintiffs' lawyers in this case, he never participated in or analyzed any epidemiological studies regarding the carcinogenic effects of NDMA nor any epidemiological studies regarding the carcinogenic effects of NDEA in humans. (*Id.* at 252:20-253:6). When asked if he holds himself out as an epidemiologist, he confirmed that he does not, though he claimed to be qualified to speak to "certain aspects of epidemiology . . . in terms of statistical matters pertaining to epidemiology." (*Id*. at 22:19-23:7). Even assuming that were the case, Dr. Madigan's opinions are not statistics opinions; they are epidemiology opinions. He is not opining on "statistical matters" pertaining to the epidemiology studies he reviewed; he is opining on the final epidemiological question of whether NDMA or NDEA

exposure at certain lifetime thresholds is associated with certain cancer risks. He is not qualified to testify outside his field on these matters. *Calhoun*, 350 F.3d at 322.

Further, none of plaintiffs' other proffered experts relies upon or cites to Dr. Madigan's putative statistical analysis. (*See* expert reports of Dipak Panigrahy, M.D., Mahyar Etminan, PharmD, MSc, Stephen S. Hecht, Ph.D, and Dr. Stephen Lagana). As such, his opinions are neither foundational for nor even relevant to some other purportedly relevant expert opinion.

In sum, Dr. Madigan is not qualified to offer general causation opinions, he admits his opinions are not general causation opinions, and the putative statistical association opinions he offers are irrelevant and are epidemiology opinions outside of his expertise. Accordingly, his opinions should be excluded in their entirety.

II. DR. MADIGAN'S OPINIONS SHOULD BE EXCLUDED BECAUSE HIS METHODOLOGY IS FLAWED AND UNRELIABLE.

A. Dr. Madigan Undertook An Unscientific, Litigation-Driven Analysis Of Literature Picked For Him By Another Of Plaintiffs' Experts.

Dr. Madigan's opinions should further be excluded in their entirety as unreliable. Dr. Madigan employed a biased methodology specifically crafted to reach the desired litigation outcome—a statistically significant association, no matter how weak or unreliable, between NDMA, NDEA, and certain types of cancer. Describing his assignment, Dr. Madigan states he was asked to perform a "statistical analysis" of "certain dietary and occupational studies which specifically examined

exposure to NDMA and/or NDEA." (Madigan Rep. ¶ 7). "Specifically, I considered the studies considered by Dr. Etminan that estimated NDMA or NDEA effect sizes." (*Id.*). Dr. Madigan uncritically relied exclusively on the literature selected for him by Dr. Etminan, whom he has never met. (Madigan Dep., at 69:24-70:9). Dr. Madigan testified that the only studies cited in his report are studies that were cited by Dr. Etminan and came out of searches conducted by Dr. Etminan. (*Id*. at 71:6-9 ("So I was asked to review the studies that Dr. Etminan - - that came out of Dr. Etminan's search. They're the ones I reviewed.").

Dr. Madigan undertook no independent assessment of the literature cherry-picked by Dr. Etminan to determine whether Dr. Etminan's studies encompassed all relevant data to be analyzed. (*See* Madigan Dep. at 71:20-16.) Nor did Dr. Madigan perform any independent assessment of Dr. Etminan's search methodology or analytical methodology. Dr. Madigan simply hitched his wagon to the literature supplied by Dr. Etminan and Plaintiffs' counsel, without conducting any independent research to verify whether there were other data points outside of the universe provided by Etminan that might influence his conclusions. That methodology is entirely unreliable. *See Daubert v. Merrell Dow Pharms., Inc. ("Daubert II")*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the

litigation, or whether they have developed their opinions expressly for purposes of testifying.").

Court previously have excluded Dr. Madigan's testimony in multiple other cases in which he conducted similar results-driven analyses. In excluding his testimony in 2015 for relying upon certain studies he preferred while excluding other relevant studies from his statistical analysis, the New Jersey Superior Court wrote: "Dr. Madigan's opinions aren't 'methodology based,' but rather are conclusion-driven. This is an expert on a mission. * * * Dr. Madigan was needed to clear the way for Dr. Kornbluth's hypothesis and that was the role he played, without regard to whether or not his efforts led the discussion any closer to scientific truth." *In re Accutane Litig.*, No. 271, 2015 WL 753674, at *19 (N.J. Super. Ct. L. Div. Feb. 20, 2015), *aff'd*, 234 N.J. 340, 191 A.3d 560, 590-93 (N.J. 2018) (finding "[a]mple evidence in the record" supports the trial court's "unassailable" conclusion that Dr. Madigan "deviated from core scientific principles and strayed from [his] own claimed methodology in order to reach [his] conclusions").

Earlier this year, another MDL court similarly excluded Dr. Madigan's testimony under remarkably similar circumstances to the present case:

> The Court notes that Dr. Madigan's analysis was limited to ***a small universe of data provided to him***. He did not conduct a comprehensive search of the published peer-reviewed literature for studies evaluating whether incretin-based drugs are associated with an increased risk of pancreatic cancer, and thereby disregarded independent research at odds with his testimony. Dr. Madigan offered no meaningful explanation as to why he did not search for

> or consider these studies other than to say, "It was not what I was asked to do." This testimony, coupled with the aforementioned biased selection of data, gives the Court great pause.

In re Incretin-Based Therapies Prods. Liab. Litig., 2021 WL 880316, at *20 (S.D. Cal. Mar. 9, 2021) (emphasis added, citations omitted). The court found that Dr. Madigan's analysis "does not fall 'within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Id*. at *21 (quoting *Daubert II*, 43 F.3d at 1317).

Here, as a result of his flawed and conclusion-driven methodology, Dr. Madigan has no basis to opine whether the inputs for his statistical calculations were exhaustive or whether other, unconsidered data, might alter his conclusions. That failure—uncritically accepting the literature provided to him as the sole basis for his opinions—is sufficient by itself to exclude Dr. Madigan's opinions as unreliable. *See McEwen v. Balt. Wash. Med. Ctr. Inc.*, 404 F. App'x 789, 791 (4th Cir. 2010) (indicating that an expert's "fail[ure] to meaningfully account for medical literature at odds with their testimony" is unreliable).

B. Dr. Madigan Knowingly Ignored Epidemiology Literature Contradicting His Opinions.

Dr. Madigan's unscientific methodology was even more results-driven in this case than in other cases in which he was excluded. The record reflects that Dr. Madigan not only failed to undertake his own literature search, but knowingly disregarded two epidemiological studies directly contradicting his opinions. In

contrast to the general dietary and occupational nitrosamine exposure literature selected by Dr. Etminan, these two studies specifically evaluate the very causation question at hand—whether patients exposed to valsartan containing an NDMA and/or NDEA impurity were at higher statistical risk of developing cancer.

There have been two published, peer-reviewed epidemiological studies comparing users of valsartan containing the NDMA and/or NDEA impurities against users believed not to have been exposed to those impurities and assessing the incidence of cancer among those two cohorts. *See* Exs. F, G (Gomm, et al. and Pottegard, et al.). Dr. Madigan failed to include them in his analysis and does not even cite them in his report (not surprisingly, as neither found an increased risk of overall cancer among those exposed to the impurity). (*See generally,* Ex. B (Madigan Rep.); Madigan Dep. at 141:15-142:18 (conceding that *Pottegard* "pertained broad strokes to the topic I was studying here" but he did not include it in his statistical analysis); Madigan Dep. at 282:21-283:9 (did not review Gomm)).[5]

Dr. Madigan conceded he was aware of these two studies, but chose not to analyze them. For example, when asked about the Pottegard study, which looked at the issue of cancer risk from nitrosamine exposure through pharmaceutical

[5] Dr. Madigan testified that he did not consider the Gomm article because he does not read German. Had Dr. Madigan conducted his own literature search, he would have discovered the English language version readily available online. (*See* https://pubmed.ncbi.nlm.nih.gov/33632389/ (last accessed Oct. 9, 2021)).

ingestion, Dr. Madigan admitted he had seen it but testified he did not "directly" perform statistical analysis to evaluate the paper. (Madigan Dep. at 141:9-142:18). He further testified that he did not perform statistical analysis to evaluate these studies because it "wasn't germane" to the question he was asked to address. (Madigan Dep. at 170:18-171:16). That was one of the exact flaws cited by the *In re Incretin* MDL court in excluding his testimony. 2021 WL 880316, at *20.

Dr. Madigan's analysis thus knowingly disregards the most relevant epidemiological data concerning the exact issue of causation before this Court. That is immediately fatal to the reliability of his methodology. *See* Motion to Exclude Hecht, at section I(A)(2), p. 12 (providing that courts will consider whether the expert ignored or sufficiently addressed epidemiological studies which contradicted his hypothesis when analyzing a causation opinion). "While the presence of epidemiology does not necessarily end the inquiry, where epidemiology is available, ***it cannot be ignored. As the best evidence of general causation, it must be addressed***." *Norris*, 397 F.3d at 882 (emphasis added). Where there is a body of contrary epidemiological evidence, "it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology." *Id*. Dr. Madigan's knowing reliance on cherry-picked literature while disregarding the two most salient pieces of medical literature confirm his opinions are conclusion-driven and wholly unreliable. *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales*

Practices & Prods. Liab. Litig. (No. II), 892 F.3d 624, 634 (4th Cir. 2018) ("Result-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion."). Dr. Madigan's statistical opinions, which are a product of his biased methodology, must be excluded.

C. Dr. Madigan Improperly Parrots The Opinions Of Dr. Panigrahy To Equate Inhaled And Oral NDMA.

An additional methodological flaw in Dr. Madigan's report and testimony is his repeated reliance on one cohort study examining occupational exposure to nitrosamines (Hidajat et al.) to show a statistical association with increased cancer risk. (*See* Madigan Rep. ¶¶ 27, 30-32, 34-35). That single study supplies the sole basis for Dr. Madigan's finding of a statistically significant increased risk of seven types of cancer based on cumulative exposure to NDMA. (*Id.* ¶ 34). But as Dr. Madigan admits, the study concerns inhaled nitrosamine exposure, not ingested exposure. (*Id.* ¶ 32; Madigan Dep. at 288:22-23). Accordingly, Dr. Madigan's conclusions about the Hidajat study and its applicability to this litigation depend on an assumption that inhaled exposure to nitrosamines is toxicologically equivalent to orally-consumed NDMA or NDEA. The exclusive basis for that assumption is his reliance on another of Plaintiffs' experts: "Dr. Panigrahy has told me that NDMA and NDEA are similarly carcinogenic via either route." (Madigan Rep. ¶ 32).

Dr. Madigan conducted no independent analysis on whether inhaled NDMA

and oral NDMA are in fact similarly carcinogenic. He just took Dr. Panigrahy's word for it. Indeed, when asked if he conducted any independent research on whether nitrosamine ingestion and inhalation were similarly carcinogenic, Dr. Madigan admitted it was "outside my area of expertise," acknowledged he had done no independent research on the question, and said he took Dr. Panigrahy's statement "at face value." (Madigan Dep. at 84:9-85:2).

Federal Rules of Evidence 702 and 703 only permit an expert to rely upon "facts or data" that are "of a type reasonably relied upon by experts in the field," not "opinions developed by another expert for purposes of litigation without independent verification of the underlying expert's work." *Fosmire v. Progressive Max Ins. Co.*, 277 F.R.D. 625, 630 (W.D. Wash. 2011) (citing Fed. R. Evid. 702, 703). An expert "may not parrot or act as a mouthpiece for other experts' opinions, without independent verification of those opinions." *Edmond v. Plainfield Bd. of Educ.*, 2018 WL 4380991, at *6 (D.N.J. Sept. 13, 2018) (citing *Leese v. Lockheed Martin Corp.*, 6 F. Supp. 3d 546, 553 (D.N.J. 2014); *Muhsin v. Pac. Cycle, Inc.*, No. 2010-060, 2012 WL 2062396, at *4, *8 (D.V.I. June 8, 2012) (holding that experts may not rely "upon opinions developed by another expert without independent verification or validation of the underlying expert's work" because Rule 703 "contemplates that a testifying expert can validate the facts, data and opinions he relied upon . . . and be subject to [cross-examination] on them")); *see also Dura*

Auto. Sys. of Ind., Inc. v. CTS Corp., 285 F.3d 609, 612-14 (7th Cir. 2002) (stating that an expert is not permitted to be the mouthpiece of a scientist in a different specialty).

Dr. Madigan's unquestioned reliance on what Dr. Panigrahy told him at face value thus fails to supply a scientific basis for him to rely upon an inhalation study to draw conclusions about ingested NDMA exposure, and his frequent reliance on the Hidajat study is unreliable. "[E]xperts who use data in their reports without independently verifying the accuracy or reliability of those figures fail to satisfy this Circuit's reliability requirement." *Edmond*, 2018 WL 4380991, at *6 (citing *Bruno v. Bozzuto's, Inc.*, 311 F.R.D. 124, 138 (M.D. Pa. 2015)); *see also In re TMI Litig.*, 193 F.3d at 716 (3d Cir. 1999) (finding "unblinking reliance" by an expert on other expert's opinions demonstrated flawed methodology under *Daubert*). "It is only when the expert undertakes some independent investigation of the underlying opinions that his testimony may be considered reliable." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014).

D. Dr. Madigan Invokes A Cumulative Exposure Theory Repeatedly Excluded As Unreliable.

Dr. Madigan's statistical analysis is also methodologically flawed insofar as it relies on and bolsters Dr. Panigrahy's defective "cumulative exposure" theory. *See* Motion to Exclude Hecht, at section II(B)(3) (explaining courts continuously find cumulative exposure theory unreliable). Dr. Madigan repeatedly purports to identify

the "lifetime exposure level" at which NDMA and/or NDEA exposure is purported to be statistically associated with various forms of cancer. (Madigan Rep. ¶¶ 8, 23, 27, 34-35). Dr. Panigrahy asserts that accumulated exposure to NDMA in valsartan increases the risk of cancer, without regard to the dose, timing, or duration of each individual exposure. (Panigrahy Rep. at 7, 12, 86-91, 96, 149-50, 180, 187, 194, 209).[6]

Federal courts have repeatedly excluded similar "cumulative exposure," "any exposure," and "each and every exposure" theories as unreliable. *See, e.g.*, *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 675 (7th Cir. 2017); *Barabin v. Scapa Dryer Fabrics, Inc.*, 2018 WL 840147, at *11 (W.D. Wash. 2018); *Rockman v. Union Carbide Corp.*, 266 F. Supp. 3d 839, 849 (D. Md. 2017); *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 848 (E.D.N.C. 2015). Specifically, this Court has recognized that reliance on an "each and every breath" theory of causation, which asserts that "each and every exposure" is substantially causative, is impermissible. *See Hoffeditz v. Am*, 2017 WL 3332263, at *10-11 (D.N.J. Aug. 4, 2017). Thus, Dr. Madigan's statistical opinions should be excluded as they rely on an unreliable and repeatedly excluded premise.[7]

[6] A copy of Dr. Dipak Panigrahy, MD's Expert Report is attached as Ex. D.
[7] Defendants further adopt and incorporate by reference their Joint Motion to Exclude the Opinions of Dipak Panigrahy, M.D., filed herewith.

E. Dr. Madigan Makes An Unfounded Inferential Leap To His Final Conclusion.

A separate and independent fatal flaw in Dr. Madigan's methodology is the inferential leap in the final paragraph of his report, where for the first time he purports to tie his statistical analysis to valsartan. There, Dr. Madigan asserts without further substantiation or explanation, "Based on valsartan dosing, the levels of NDMA reported in contaminated valsartan and the timeframe over which the contamination occurred, it is scientifically plausible that users of contaminated valsartan could develop cancer." (Madigan Rep. ¶ 35). Dr. Madigan's report is utterly silent as to what he means by "valsartan dosing" or "the timeframe over which the contamination occurred"; he does not say what assumptions he made as to dosing or timeframe of alleged contamination. With respect to "levels of NDMA reported," Dr. Madigan's report refers earlier to levels ranging "from below the limit of detection to 20.19 µg[.]" (*Id.* ¶ 6). In the final paragraph, without explaining the basis for his assumption, he simply assumes the very highest end of this range, "20 µg of NDMA" every day for a year, to illustrate how "cumulative exposure" could "show statistically significant elevated risks of several cancers." (*Id.* ¶ 35).

Asked to explain this opinion at deposition, Dr. Madigan offered an evasive answer that simply assumed causation as its premise:

> I mean -- you know, I studied across a variety of dietary studies, and significant occupational study, and the association between certain amounts of cumulative exposure to NDMA and cancer outcomes, and, you know, in

> many cases, there are statistically significant associations, you know, between them. And so, you know, ***if indeed these levels of NDMA -- in these studies if indeed they cause cancer***, this is exactly what you'd expect to see. These kinds of associations are exactly what you'd expect to see. And based on this analysis, it seems entirely plausible to me that user -- ***based on what I know about the contamination levels in valsartan, it's entirely plausible to me*** that the contaminated valsartan -- those folks could have developed -- the folks that took contaminated valsartan could have developed cancer.

(Madigan Dep. 208:9-209:5 (emphases added)). Thus, Dr. Madigan's starting point is that "these levels of NDMA" cause cancer—despite disclaiming any causation opinion—and he further relies on "what [he] know[s] about the contamination levels in valsartan" as his explanation without setting out or justifying his assumptions. *Id.*

Dr. Madigan's unsubstantiated inferential leap falls well short of reliable. *See* Motion to Exclude Hecht, at section I(A)(3) (discussing that expert opinion must assist the trier of fact). "Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Here, Dr. Madigan leaps from dietary and occupational NDMA lifetime cumulative exposure data unrelated to valsartan (while ignoring the only two epidemiological studies actually evaluating valsartan NDMA exposure) to a conclusion about the "scientific plausibility" of developing cancer from taking valsartan, based on wholly unexplained assumptions regarding dosing and

timeframe and utilizing the highest reported NDMA levels as his baseline assumption. Dr. Madigan's "*ipse dixit* does not withstand *Daubert*'s scrutiny." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 158 (3d Cir. 2000). An opinion based on "subjective belief or unsupported speculation" rather than "the methods and procedures of science" lacks "good grounds." *Id*. (citing *Paoli*, 35 F.3d at 742).

Dr. Madigan also does not explain why dietary and occupational exposure studies evaluating NDMA exposures in food or air apply to the question at issue in this case of whether ***pharmaceutical*** exposure to preformed NDMA and/or NDEA is capable of causing the specific cancers Plaintiffs allege. Dietary and occupational exposures are not the relevant inquiry, and as Plaintiffs' own experts have been forced to concede, retrospective studies based on dietary questionnaires are notoriously unreliable due to recall bias, selection biases and other factors; equally unreliable are the decades-old food tables that were used to estimate the levels of nitrosamine in each food stuff examined. (Etminan Dep. at 142:7-20, 144:20-145:25, 153:8-17, 247:5-249:3; Hecht Dep. at 215:6-217:25 ["just about all of these studies can be criticized for one reason or another"].)

Dr. Madigan offers no literature, methodology, or analysis to support his assumption that dietary and/or occupational exposures are even relevant to pharmaceutical exposure. (Madigan Dep. at 83:9-84:21). Nor could he, as he lacks the required expertise. (*Id*. at 205:22-206:16). It is well settled that "expert testimony

that contains bare conclusions, unsupported by the factual evidence may be excluded." *See State of New Jersey v. Haig's Serv. Corp.*, 2016 WL 4472952, at *3 (D.N.J. Aug. 24, 2016). Dr. Madigan's reliance on dietary and occupational studies reflects a flawed methodology, compounded by his failure to consider the two relevant human epidemiological studies known and available to him.

In sum, Dr. Madigan's opinions are not based on a reliable methodology, or any methodology. Instead, Dr. Madigan purports to conduct a statistical analysis of cherry-picked literature, ignores key epidemiological studies directly relevant to the immediate causation question, parrots unfounded assumptions based on the unconfirmed assurances of another Plaintiffs' expert, employs an unreliable cumulative exposure methodology, and makes unwarranted inferential leaps. His opinions should therefore be excluded in their entirety.

III. DR. MADIGAN'S OPINIONS REGARDING NDEA AND CANCER SHOULD BE EXCLUDED, AS SHOULD ANY OPINION ON SPECIFIC CANCERS HE NEVER ANALYZED.

A. Dr. Madigan Should Be Excluded From Offering Any Opinions Related To Alleged Cancers Associated With NDEA Exposure.

Dr. Madigan should not be permitted to offer opinions or testimony on the supposed association or causation between NDEA and any cancer. According to his own testimony, Dr. Madigan did not undertake any independent analysis of NDEA. (Madigan Dep. at 195:6-196:13) This alone disqualifies him from offering any opinions regarding NDEA and a purported association with cancer. Moreover, Dr.

Madigan reviewed only one study (Zheng, et al.) concerning a possible association between NDEA and any cancer, and that study identified an association with respect to only one type of cancer: pancreatic. (*Id.*) The Zheng study does not provide a basis for any of Dr. Madigan's opinion regarding NDEA and cancer, and Dr. Madigan reviewed no other studies finding an association between NDEA and cancer.

As a threshold matter, the authors of the Zheng study specifically stated that the association "needed to be confirmed in a readily available large prospective cohort study. (Madigan Dep. at 266:3-267:7). The Zheng study is thus, by its own terms, not reliable to draw a conclusion as to the alleged association between NDEA exposure and pancreatic cancer. Yet, the shortfalls of the Zheng study run much deeper. Crucially, Dr. Madigan conceded that the NDEA exposures in Zheng were not comparable to those at issue here insofar as the association in Zheng was based upon a lifetime cumulative exposure to 2,520,000 nanograms of NDEA. (Madigan Dep. 272:18-273:15). Given that the tested levels of NDEA contained in the affected valsartan were relatively low,[8] combined with the fact that none of the affected valsartan was on the market for more than six (6) years, the probability that any plaintiff in this litigation could have been exposed to 2,520,000 nanograms of NDEA from taking valsartan is at or near zero. (Madigan Dep. 279:8-280:18). By way of

[8] *See* Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of Stephen Hecht, M.D., at p. 47 (highlighting that the mean NDEA found in Mylan's valsartan is 150 ng/day, which is the highest of all the manufacturers).

illustration, even if a hypothetical patient took Mylan's valsartan at the highest labeled dosage (320mg) with the highest level of NDEA detected in any active pharmaceutical ingredient ("API") batch ever produced (1.57ppm) for the entire six-year period Mylan's VCDs were on the market, the patient's exposure to NDEA would be less than half of the exposure studied in Zheng. Likewise, the highest detected NDEA content in any finished dose batch produced by Mylan was 380 nanograms per tablet. Even assuming a hypothetical plaintiff was exposed to this amount of NDEA every day, according to Dr. Madigan, "it would take you 6,631 days to get to. . . cumulative exposure of 2,520." (Madigan Dep. at 280:2-9) No plaintiff in this litigation could have taken affected valsartan for more than six (6) years; therefore no Plaintiff could have been exposed to the same levels of NDEA analyzed in Zheng.

As to every other specific cancer at issue in this litigation, Dr. Madigan conceded he had not reviewed or cited any study linking exposure to NDEA with an increased risk of the cancer. (Madigan Dep. at 269:5-11 ("Q: you don't cite any observational study anywhere in your report linking NDEA exposure to any form of cancer other than pancreatic cancer, correct? A: That's correct. I'm not aware of such studies"); *see also* Madigan Dep at 269:12-272:6 (conceding he reviewed no studies linking exposure to NDEA to bladder cancer, blood cancer, colorectal/intestinal cancer, gastric cancer, kidney cancer, liver cancer, lung cancer,

pharyngeal cancer, prostate cancer, or uterine cancer).

Notably, when asked, "From the research that you've done in this case, do you have an opinion as to whether there are certain exposure levels of NDEA that are so low as to prevent a *de minimis* risk of harm to humans?" Dr. Madigan responded, "I don't know. It's not something I've looked at. I quoted what the FDA said. I quoted Johnson. I don't know. That's not something I studied myself." (Madigan Dep. at 261:18-262:2).

NDMA and NDEA are not the same. The Court, the parties, and the experts must analyze each of them independently. Having failed to analyze NDEA, Dr. Madigan should not be permitted to offer any testimony or opinions about a supposed link between any cancer and exposure to NDEA. *See Wehling v. Sandoz Pharms. Corp.*, 1998 WL 546097, at *5 (4th Cir. Aug. 20, 1998) ("conjecture, hypothesis, subjective belief, or unsupported speculation are impermissible grounds on which to base an expert opinion").

B. Dr. Madigan Should Be Excluded From Offering Any Opinions Related To Certain Specific Cancers, Including Breast, Kidney, Pharyngeal, And Uterine Cancers.

Similarly, Dr. Madigan should not be permitted to offer blanket opinions or assertions regarding cancer generally or specific cancers on which he has disclosed no relevant, reliable opinions. Dr. Madigan's opinions must be reliable and relevant as to each cancer at issue. But Dr. Madigan has disclosed no analysis of several of

the cancers claimed by Plaintiffs to be at issue in this litigation. As his report and deposition testimony make clear, Dr. Madigan has not assessed and has no basis to offer any opinions on cancers of the bladder, breast, blood, kidney, pharynges, prostate or uterus, all of which are listed on Plaintiffs' Disclosure of Cancer Types at issue in this litigation. Compare Cancer Disclosure, attached as Ex. E, with Ex. B (Madigan Rep. Table 1 (listing analyses only for gastric, esophageal, bladder, prostate, pancreas, lung and colorectal)); Madigan Dep. at 198:6-14, 199:17-22 (no opinions regarding breast cancer).

The list of cancers in Dr. Madigan's report are a reflection of the cancers that were addressed in the studies that Plaintiffs asked him to review, *i.e.*, those selected by Dr. Etminan. (Madigan Dep. at 198:9-14, 199:3-15). Dr. Madigan was not even familiar with Plaintiffs' Cancer Disclosure. (Madigan Dep. at 198:15-199:1). Accordingly, at a minimum, Dr. Madigan should be precluded from offering any opinions or testimony about bladder, breast, blood, kidney, pharyngeal, and uterine cancers. He has offered no basis for any such opinions.

CONCLUSION

Dr. Madigan is not offering general causation opinions. Therefore, he is not qualified to assist the Court or the jury at this stage in the proceedings, his opinions do not fit the general causation question, and his opinions should be excluded in their entirety. Dr. Madigan's "strength of association" opinions are likewise irrelevant

and he is not qualified to provide covert epidemiology opinions. Dr. Madigan has additionally failed to use a reliable methodology, has knowingly excluded relevant epidemiological literature from his analysis, and has employed unsupported premises to provide his opinions. And he has supplied no reliable basis to opine regarding NDEA exposure and certain cancers. For all of these reasons, Defendants respectfully request that the Court exclude or limit the opinions of Dr. Madigan in whole or in part.

Dated: November 1, 2021

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 1, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Seth A. Goldberg
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